

REMARKS

With entry of the foregoing Amendment, claims 15 and 17-20 are currently pending in the application. Claim 15 has been amended to delete the phrase “being aligned with a surface of the edge region of the inert film (9’) or,” such that claim 15 now recites that the annular continuous sealing zone (13) projects slightly radially beyond the surface of the edge region of the inert film. Further, claim 15 has been amended to correct a previously inadvertent omission of the term “position.” Claim 16 has been canceled without prejudice. Claim 19 has been amended to more particularly point out that a cross-section of the receiving cavity (6) commencing from a bottom (6b) continuously tapers out toward an opening of the receiving cavity (6)

Currently amended claims 15 and 19 are at least supported by the original claims, Figs. 9-12 and specification paragraph [0012] and [0044]. Accordingly, no new matter has been added and entry of the amendments is respectfully requested.

Telephone Interview

At the outset, Applicant wishes to thank Examiner Mehta for her time and the courtesy of a telephone interview with Applicant’s representative, Mark Vogelbacker, on Thursday, May 15, 2008. Referring to the Interview Summary (form PTOL-413) issued by Examiner Mehta, Applicant notes that it appears that she inadvertently stated the date of the interview was April 15, not May 15. During the interview, Applicant proposed to amend claims 15 and 19 (as set forth above).

Examiner Mehta indicated that the proposed amendments appear to overcome the rejection based on U.S. Patent No. 4,929,231 (Pawlikowski) in view of European Patent No. 0148426 (Pharma Gummi). However, Examiner Mehta stated that if the amendment is formally filed, she will be obligated to consider the amendment in more detail and/or conduct additional searching.

In response to the interview, Applicant is formally submitting the proposed amendments to claims 15 and 19, as discussed during the interview, to further distinguish over the known prior art references. This Amendment is being accompanied by an RCE. Applicant requests that if upon further consideration Examiner Mehta determines that the above-cited amendments to claims 15 or 19 are not patentable over the known prior art, Examiner Mehta place a telephone

call to Applicant's representative to discuss possible amendments to expedite prosecution. Below is a brief summary of the arguments presented to Examiner Mehta during the telephone interview.

Claim Objections

Claim 15-20 were objected to because the Examiner noted that there appears to be text missing between "working" and "the" in line 18 (now line 16) of claim 15. In view of the Examiner's comments, Applicant has amended claim 15 to insert the term "position" following "working." Applicant respectfully submits that the term "position" was inadvertently omitted in the previous Amendment and such term is at least supported by the original claims and specification paragraph [0044].

Therefore, the objection to the claims is moot and Applicant respectfully submits that the claims are in full compliance with the requirements. Applicant respectfully requests that the objection to the claims be withdrawn.

Claim Rejections - 35 U.S.C. § 103

1. Claims 15, 16, 19 and 20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,929,231 (Pawlikowski) in view of European Patent No. 0148426 (Pharma Gummi). The Examiner acknowledges that Pawlikowski fails to disclose a base body being made substantially from an elastomer, being made in one piece or comprising a receiving cavity. Further, the Examiner admits that Pawlikowski fails to disclose a piston section being enclosed in a cap-shaped inert film where the film comprises a fluorinated polymer film. The Examiner relies upon Pharma Gummi to teach these features that Pawlikowski lacks and asserts that it would have been obvious to combine Pawlikowski and Pharma Gummi to create the piston stopper disclosed and claimed in the present application. The rejection of amended claim 15, and claims 19 and 20 depending therefrom, is respectfully traversed.

Referring to Figs. 1-3, Pawlikowski discloses hypodermic syringe 10 having a body 12 and a needle 14 extending from a front end 16 of the body 12. An inwardly facing circumferential groove 36 is provided adjacent the front end 16 of the body 12. The groove 36 has a plane surface 38 perpendicular to the axis of the body 12 and a frusto-conical surface 40 which makes an acute angle with the surface 38. Further, the syringe 10 includes a plunger

assembly 22 having a rod member 24 that extends from a rear end 18 of the body 12 and has at its rearward end a thumb-engaging enlargement 26. The front end of the rod member 24 has an integral head portion 28 that telescopingly fits within the body 12. The head portion 28 has a circumferential groove 30 and an O-ring 32 located therein and slidably engages the inner wall of body 12. A non-inert cap 34, which is deflectable to a frusto-conical shape when it engages the front end 16 of the body 12 (col. 2, lns. 41-43), is affixed to the head portion 28.

In operation, as the rod member 24 is pushed toward the front end 16 of the body 12, “the administrator of the injection will sense a change in the action of syringe 10, due to deformation of deformable cap 34 and will know that he or she must go a little further in order to cause O-ring 32 to snap into groove 36, thus to inject all of the required medication and achieve the desired locking and non-reusability of syringe 10” (col. 2, lns. 60-66).

Referring to Fig. 18, Pharma Gummi discloses a piston 33 for use in a pharmaceutical syringe. The piston 33 is comprised of three radially protruding sealing bulges 34, 35, 36. The first sealing bulge 34 is sheathed with a relatively hard, fluorinated polymer film 8, or a chemically inert film (pg. 9, lns. 5-7), which is undetachably connected to the rubber-elastic material of the piston 33 (col. 28, lns 6-10).

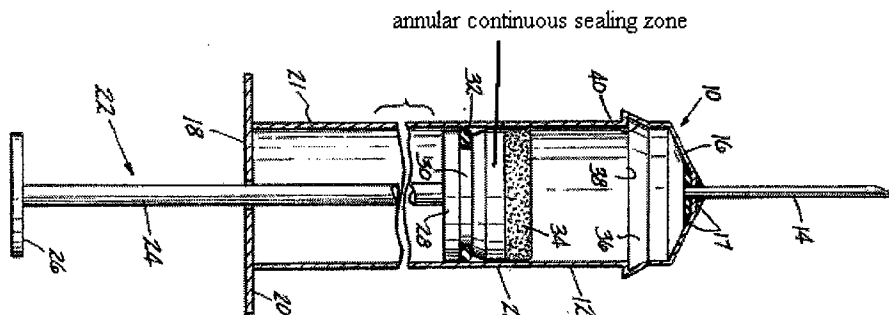
Claim 15 of the present application is directed to a pharmaceutical piston stopper and recites, *inter alia*, as follows:

a piston section (8) enclosed in a cap-shaped inert film (9'), the piston section in a working position facing contents of a syringe or carpule cylinder (1), an outer circumference of the piston section with its inert film (9') abutting against the syringe or carpule cylinder (1), the piston stopper (2) having an uncoated sealing section (10) adjacent to the piston section (8), the uncoated sealing section and an edge region of the inert film (9') flatly abutting in the working position against the syringe or carpule cylinder (1), . . . and wherein the sealing section (10) has on its outer circumference an annular continuous sealing zone (13) directly adjacent to and directly adjoining the edge region of the inert film (9') enveloping the piston section (8) and abutting against an inside wall of the syringe or carpule cylinder (1), said annular continuous sealing zone (13) projecting slightly radially beyond the surface of the edge region of the inert film (9'), so that in the working position the piston stopper (2) abuts with the sealing section (13) fully against the syringe or carpule cylinder (1). [Emphasis added]

Even assuming, *arguendo*, that the Examiner's proposed combination of Pawlikowski and Pharma Gummi were proper, the combination does not disclose each and every element of

amended claim 15. Specifically, neither Pawlikowski nor Pharma Gummi disclose, teach or even suggest the combination of a piston stopper 2 having a piston section 8 enclosed in a cap-shaped inert film 9' and an uncoated sealing section 10 adjacent to the piston section 8, the sealing section 10 having on its outer circumference an annular continuous sealing zone 13 that is directly adjacent to and directly adjoins the edge region of the inert film 9' enveloping the piston section 8 and abutting against an inside wall of the syringe or carpule cylinder 1, and that the annular continuous sealing zone 13 projects slightly radially beyond the surface of the edge region of the inert film 9', so that in the working position the piston stopper 2 abuts with the sealing section 13 fully against the syringe or carpule cylinder 1, as is recited in amended claim 15.

In line 18 on page 2 of the Office Action, the Examiner asserts that the deflectable cap 34 of Pawlikowski is equivalent to the piston section 8 of the present invention. Given this interpretation, Applicant assumes that the Examiner defines the structure noted below as equivalent to the annular continuous sealing zone 13 of the present invention:



However, this “annular continuous sealing zone” of Pawlikowski does not project slightly radially beyond the surface of the edge region of the inert film that surrounds the piston section, as is recited in amended claim 15. Instead, this “annular continuous sealing zone” of Pawlikowski is shown as being directly aligned with or as being in a straight plane with an outer surface of the edge region of deflectable cap 34. If anything, the deflectable cap 34 may slightly radially extend beyond the surface of the edge region of this “annular continuous sealing zone,” as Pawlikowski explicitly states that the deflectable cap 34 “is deflectable . . . when it engages front end 16” (col. 2, lns. 41-43). Thus, there is simply no disclosure, teaching or even a suggestion in Pawlikowski that this “annular continuous sealing zone”, which is directly adjacent

to and directly adjoins the edge region of the deflectable cap 34, projects slightly radially beyond the surface of the edge region of the deflectable cap 34.

Pharma Gummi does not make-up for this deficiency. Referring to Fig. 18 of Pharma Gummi, region 43, which is directly adjacent to the piston section 33 covered in film 8, does not project slightly radially beyond the surface of the edge region of the inert film that surrounds the piston section, as is recited in amended claim 15. Instead, region 43 is shown as being significantly inward of the surface of the edge region of the film 8.

In the present invention, the annular continuous sealing zone 13 on the outer circumference of the sealing section 10 that is directly adjacent and directly adjoining an edge region of the inert film 9' provides a tight seal, especially from the side away from the liquid near the sealing zone 13, which prevents, for example, microbial or other contaminations from the outside from entering the syringe 10 from the backside. Further, the claimed structure of the present application minimizes the possibility that liquid in the syringe will contact the non-inert material, or the sealing section 10, and minimizes the possibility of liquid loss out the backside of the syringe.

Based upon each of the above, Applicant respectfully submits that amended claim 15, and claims 19 and 20 depending therefrom, are patentable over Pawlikowski and Pharma Gummi and request that the rejection under 35 U.S.C. § 103(a) be withdrawn.

2. The Examiner also rejected claims 17 and 18 under 35 U.S.C. § 103(a) as being unpatentable over Pawlikowski and Pharma Gummi, and further in view of U.S. Patent No. 2,895,773 (McConnaughey). The McConnaughey patent was cited because it allegedly discloses a piston cap having an internal thread to connect with a thread of the displacement transferring element. The McConnaughey patent does not disclose or even suggest the combination of a piston stopper 2 having a piston section 8 enclosed in a cap-shaped inert film 9' and an uncoated sealing section 10 adjacent to the piston section 8, the sealing section 10 having on its outer circumference an annular continuous sealing zone 13 that is directly adjacent to and directly adjoins the edge region of the inert film 9' enveloping the piston section 8 and abutting against an inside wall of the syringe or carpule cylinder 1, and that the annular continuous sealing zone 13 projects slightly radially beyond the surface of the edge region of the inert film 9', so that in

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the working position the piston stopper 2 abuts with the sealing section 13 fully against the syringe or carpule cylinder 1, as is recited in amended claim 15.

Applicant respectfully submits that claims 17 and 18, which are dependent upon claim 15, are patentable over Pawlikowski and Pharma Gummi and further in view of McConnaughey for at least the same reasons discussed above for claim 15. Accordingly, Applicant respectfully submits that claims 17 and 18 are patentable over all of the references currently of record in the application.

For all the reasons above, Applicants respectfully submit that amended claim 15, and claims 17-20 depending therefrom, are patentable over all of the prior art of record and request that the rejections under 35 U.S.C. § 103(a) be withdrawn.

Claim 19

In lines 15-16 on page 3 of the Office Action, the Examiner refers to Fig. 18 and asserts that Pharma Gummi teaches “a receiving cavity where a cross-section of the receiving cavity tapers out toward an opening of the receiving cavity.” However, Fig. 18 of Pharma Gummi shows a cavity that does not taper outwardly toward the opening. Instead, the sidewalls of the cavity are a straight extension that are not tapered or gradually lean. Furthermore, Pharma Gummi fails to disclose, teach or even suggest a cross-section of the receiving cavity commencing from a bottom continuously tapers out toward an opening of the receiving cavity, as is recited in amended claim 19.

Based upon each of the above, Applicant respectfully submits that amended claim 19, which depends from amended claim 15, is patentable over Pharma Gummi and all of the other references currently of record for at least the reasons discussed above. Applicant respectfully requests that the rejection under 35 U.S.C. § 103(a) be withdrawn.

Information Disclosure Statement

A Supplemental Information Disclosure Statement (IDS), with associated Form PTO/SB/08a, was filed in the present application on February 26, 2008. This Supplemental IDS was filed because references were cited in an Office Action from the Japanese Patent Office concerning a Japanese counterpart application. Applicants respectfully request that the Examiner consider each reference cited in the Supplemental IDS and initial each reference on the

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accompanied PTO/SB/08a form.

CONCLUSION

In view of the foregoing Amendment and Remarks, Applicant respectfully submits that the present application, including claims 15 and 17-20, is in condition for allowance and such action is respectfully requested.

Respectfully submitted,

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(Date)

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